DETAILED ACTION

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claim 20 has been amended to add:

> "wherein the microcapsules for modified release comprise a film coating that: (i) is applied to a core comprising active principle(s), wherein none of the active principle(s) is amoxicillin, (ii) controls the modified release of the active principle(s) in gastrointestinal tract fluids, and (iii) comprises:
> (1) at least one film-forming polymer (P 1) insoluble in gastrointestinal tract fluids, present in an amount of 50 to 90% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one film-forming polymer (P 1) is a water-insoluble cellulose derivative;
> (2) at least one nitrogen-containing polymer (P2) present in an amount of 2 to 25% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one nitrogen-containing polymer (P2) is selected from the group consisting of: polyacrylamide, poly-N-vinyl amide, and poly-N-vinyl lactam;
> (3) at least one plasticizer present in an amount of 2 to 20% by dry weight based on the total weight of the coating composition, and wherein at least one of said at least one plasticizer is selected from the group consisting of: glycerol esters, phthalates, citrates, sebacates, cetyl alcohol esters, and castor oil; and
> (4) at least one surfactant or lubricant present in an amount of 2 to 20% by

dry weight based on the total weight of the coating composition, and wherein at least one of said at least one surfactant or lubricant is selected from the group consisting of: anionic surfactants, non-ionic surfactants, and lubricants, and
mixtures thereof;
and wherein the *in vitro* release profile of the suspension of microcapsules in an aqueous liquid phase on day ten is similar to the release profile on day zero, as measured using a type II apparatus according to the European Pharmacopoeia 3rd edition, in a phosphate buffer medium of pH 6.8, at a temperature of 37°C;"

after the recitation, "just necessary for modified release," in line 7.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance:

The declarations filed October 19, 2010 provide comparisons of the stability of suspensions of the instant and other suspensions that employ particles coated with compositions that were known at the time of the invention and were outside the bounds of the instant claims. According to the teachings of the specification and those incorporated by reference, "similar" release profiles have a similarity factor, f_2, that is greater than or equal to 50 when calculated according to the algorithm developed by Moore and Flanner. Upon comparing the release profile of the suspensions outside the invention at day zero and approximately day ten, the similarity factor was less than 50, indicating dissimilar release. When the same comparison was made of multiple suspensions within the scope of the invention, the similarity value was greater than 50,

indicating similar release. In addition applicants compared suspensions of the instant invention where the liquid medium was saturated with the same drug contained in the particles or was free of dissolved drug. In both instances, the similarity factor between the release of the suspensions initially and after storage were greater than 50. These data indicate that all known controlled release coatings that were initially obvious to utilize on the particles in the suspension of Carvais are not equivalent in function. Specifically, all controlled release coatings do not maintain their release properties when included in a suspension saturated with drug that is also contained in the particle. In addition, these data also indicate that the saturation of the liquid medium in the suspension is not itself sufficient to maintain the release properties of the suspended particles. Instead the particular claimed coating composition has the unique property of retaining its release controlling characteristics when stored over multiple days. The declarations are therefore found to be persuasive. The provisional obviousness-type double patenting rejections are hereby withdrawn. The compositions of claims 1-5, 7-11, 17-19, and 21-27 are non-obvious over Carvais in view of Autant et al., claim 20 is non-obvious over Carvais in view of Autant and Ulrich et al.; and claims 13-16 are non-obvious over Carvais in view of Autant et al. and Turck et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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